JAN 3 0 2004

K033796

Section 2

510(k) SUMMARY
of Safety and Effectiveness
(as required by Section 807.92)

Applicant:

Heinz Kurz GmbH Medizintechnik
Tübinger Str. 3
D-72144 Dusslingen
Germany
Tel. 011-49-7072-91790
Fax 011-49-7072-917979
E-mail: info@kurzmed.de

Contact Person:

Angelika Scherp
Business Support International
Amstel 320-1
1017AP Amsterdam
The Netherlands
Tel. 011-31-20-428-9591
Fax 011-31-20-428-9429
E-mail: bsi@xs4all.nl

Proprietary Name: KURZ Silicone Strips

Common Name: Silicone Strips

Classification Name: Elastomer, Silicone Block

Substantial Equivalence:

KURZ Silicone Strips are substantially equivalent in function, performance and material to Silicone Elastomer Sheeting marketed by Specialty Surgical Products, Inc., K974653.

Device Description:

General

KURZ Silicone Strips are manufactured from a medical grade silicone elastomer cut to size specifically for use within the external ear canal following ear surgery. The pliable, soft consistency of the silicone strips adapts itself to the shape of the auricular canal without further shaping by the physician, which saves valuable time in the operating room.

KURZ Silicone Strips are intended for single use and are provided sterile. They require no further processing. They will be supplied transparent, white or transparent with blue stripes. Application, use and technical characteristics of the three presentations are identical. Choice of one or the other is entirely a matter of personal preference of the operating surgeon. Some surgeons prefer the transparent silicone strip, since the healing process can be checked without removing the dressing. Others prefer the white silicone strip, since they find it easier to see and handle. The transparent strips imprinted with blue stripes combine both

advantages. The healing process can be observed through the transparent parts of the silicone, while the blue stripes make the silicone strips easily visible.

Dimensions 0.12 x 45 x 6 mm (thickness, length, width)

Colors
1. Transparent
2. White
3. Transparent with blue stripes

Packaging Each package contains ten sterile (10) pouches with three strips/pouch

Intended Use:

KURZ Silicone Strips are placed over the tympanic membrane after surgical procedures in the middle ear to reduce the risk of adhesion to the surgical packing and to aid in the prevention of canal granulation and polyp formation. Using conventional otologic pliers and tweezers, the three sterile strips contained in one pouch are placed one over the other covering the tympanic membrane in a star-shaped pattern, with the atraumatic, rounded end toward the anterior meatal flap. The center of the strip is inserted to overly the tympanic membrane.

Once the wound has healed, the silicone strips are removed from the auricular canal by the physician, should they not be expelled with the tamponage or upon disintegration of the gelatinous tamponage. This usually takes place after 10-21 days.

Predicate Device:

KURZ Silicone Strips are substantially equivalent in material, function and performance to Silicone Elastomer Sheeting marketed by Specialty Surgical Products, Inc. However, they are precut and rarely need additional shaping.

Sterilization:

KURZ Silicone Strips are sterilized by low-temperature gas plasma to avoid the degrading effects of steam or the residues of ethylene oxide. The sterility assurance level (SAL) for the KURZ Silicone Strips will be 10^{-6}.

Biocompatibility:

The silicone elastomer, coloring agents and packaging material were tested for biocompatibility in conformance with international and FDA-recognized standards, including the FDA "Blue Book Memorandum" based on ISO 10993 Part 1 "Biological Evaluation of Medical Devices". KURZ Silicone Strips present no safety risks or hazards and are safe and effective for the indicated use.

Information Bearing on Safety and Effectiveness [807.92(b))3)]

There are no additional characteristics known that should adversely affect the safety and effectiveness of KURZ Silicone Strips. **The results of design validation raise no issues of safety and effectiveness.**

SE COMPARISON TABLE

	KURZ	SPECIALTY SURGICAL PRODUCTS K974653	AESTHETIC & RECONSTRUCTIVE TECHNOLOGIES K022223	SE
Material	Silicone sheeting	Silicone sheeting	Silicone sheeting	**YES**
Sterility	Sterile	Not labeled	Sterile	**YES**
Indications for Use	Temporary protective sheathing for the external ear canal	Temporary protective sheathing for the external ear canal	Temporary protective sheathing for the external ear canal	**YES**
Measurements	0.12 x 45 x 6 mm	Cut to size by user	Cut to size by user	**YES**
Reusable	No	No	No	**YES**
Coloring Agents	1% Titanium Dioxide NuSil MED3-4502 (USP Grade) Silicone Coating / Marking Ink NuSil R1008-7	Not labeled	Not labeled	
Biocompatible	Yes	Yes	Yes	**YES**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2004

Heinz Kurz GmbH Medizintechnik
c/o Angelika Scherp
Business Support International
Amstel 320-1
1017 AP Amsterdam
The Netherlands

Re: K033796
Trade/Device Name: KURZ Silicone Strips
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose, and throat synthetic polymer material
Regulatory Class: Class II
Product Code: KHJ
Dated: December 3, 2003
Received: December 5, 2003

Dear Ms. Scherp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K033796

Device Name **Silicone Strips**

INDICATIONS FOR USE

KURZ Silicone Strips are designed to temporarily cover the tympanic membrane after surgical procedures in the middle ear.

(Division Sign-Off)
Division of Opthalmic Ear,
Nose and Throat Devises

510(k) Number K033796

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per CFR 801 109)

(Optional Format 1-2-96)